IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

BEVERLY LAMBERSON, AS ADMINISTRATRIX OF THE ESTATE OF MELINDA LAMBERSON REYNOLDS, DECEASED, *Plaintiff*	:	CIVIL ACTION NO. 09-CV-1492
v.	:	(Judge Munley)
COMMONWEALTH OF PENNSYLVANIA, *et al.*, *Defendants*	:	Electronically Filed

APPENDIX TO PLAINTIFF'S STATEMENT OF MATERIAL FACTS, PURSUANT TO LOCAL RULE 56.1, IN SUPPORT OF HER MOTION FOR PARTIAL SUMMARY JUDGMENT

Appendix Tab A

Report of Robert G. Newman, M.D., M.P.H.

Continuum Health Partners

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Report of Robert G. Newman, M.D., M.P.H., Concerning *Melinda Lamberson Reynolds v. Commonwealth of Pennsylvania,* et al., No. 09-CV-1492 (JMM)

PERSONAL QUALIFICATIONS

The opinions in this report reflect my review of the records sent to me which are further identified below. I reserve the right to supplement this report at a later date to the extent that additional information becomes available.

These opinions are based on more than 40 years of experience in the field of opioid[1] dependence and its treatment, and most particularly treatment involving methadone. I was ultimately responsible for every aspect of the treatment with methadone of the New York City Methadone Maintenance and Ambulatory Detoxification Programs, which in the early 1970's cared for over 33,000 patients per year. Subsequently I played a key role in recommending and helping to implement similar policies and procedures that were adopted by large-scale programs utilizing methadone in many countries around the world, and I continue to the present time to lecture on the pharmacology of methadone in treating opioid dependence, and on this medication's effects and side effects.

In addition to my very active involvement in treatment of addiction I served for two decades as the Chief Executive Officer (CEO) for Beth Israel

[1] As used in this report, the term "opioid" drugs includes both "opiates," *i.e.,* drugs that are directly derived from the opium poppy, and also other drugs that – like opiates – work by binding themselves to the body's opioid receptors. "Narcotic" is a pharmacological term that is applied both to opiates and to opioids.

Medical Center (BIMC) – the institution that in the mid-60s pioneered the clinical use of methadone in treating opioid dependence and continues to have the largest methadone program in the United States. BIMC also operates the Phillips-Beth Israel School of Nursing, a school established more than a century ago and currently having a student enrollment of approximately 300, and I was a member of the Advisory Committee for the School of Nursing from 1978 to 1997.

Until my retirement in 2001 I also served as the founding CEO of Continuum Health Partners, the parent corporation established in 1997 by the alliance between BIMC and St. Luke's-Roosevelt Hospital Center (subsequently to be joined by two other academic medical centers). Continuum Health Partners institutions for which I was responsible had over 2,500 beds and employed approximately 17,000 full-time workers, of whom more than 4,500 were nurses. Shortly after being designated President Emeritus I was asked to assume the directorship of the Beth Israel Baron Edmond de Rothschild Chemical Dependency Institute, established in 2001; I continue to serve as the Institute's Director today.

As CEO I was ultimately responsible for all policies and procedures adopted by the medical centers I directed. I was consulted with regard to all major policy issues that dealt with drug dependence and its treatment – including, very specifically, those concerning employment of persons who were dependent on opioid drugs. I have been consulted in a variety of legal cases, sometimes for plaintiff and sometimes for defendant, and have been deposed and testified in court. At least one such case (involving consultation and deposition, but not testimony) involved an alleged employment discrimination matter. A copy of my current resumé / curriculum vitae, and a list of legal matters in which I have testified, are being provided together with this report.

DOCUMENTS REVIEWED REGARDING REYNOLDS *v.* PENNSYLVANIA, *ET AL.*

A list of documents that I have reviewed in order to prepare this report is being provided together with this report. In addition, I have relied upon the authorities cited in the report itself as well as my experience in the field of

opioid dependence and its treatment, as well as my experience as CEO of BIMC and Continuum Health Partners as described above.

METHADONE IN THE TREATMENT OF OPIOID DEPENDENCE

Methadone is an opioid "agonist," *i.e.,* a drug that binds to opioid drug receptors and therefore is useful in treatment of opioid drug dependence both as a short-term medication to control withdrawal symptoms ("detoxification") and as a long-term ("maintenance") medication to assist opioid dependent patients to refrain from use of illicit drugs and to lead functional, socially productive, healthy lives. Methadone has been utilized in the treatment of opioid dependence since the mid-1960s.

Addiction to opioids – whether to illicit drugs such as heroin or prescription opioids approved for use as analgesics – has been recognized for almost a century to be a chronic medical condition and *not* a "bad habit" that can be eliminated given sufficient motivation. Furthermore, it is a condition for which, to date, no "cure" has been identified, but one which can be treated (precisely the same description applies and is almost universally accepted with regard to addiction to alcohol). Gradually diminishing daily dosages of methadone over a brief period of time (generally only a few weeks) can reduce markedly, and often eliminate entirely, the withdrawal symptoms that would be associated with abruptly discontinuing opioid use. In this manner abstinence can be achieved quite readily – but once achieved, relapse to opioid use when the methadone dose is reduced or discontinued is the overwhelming rule rather than the exception. It is for this reason that "maintenance" treatment came to be employed on a long-term basis, and the special properties of methadone made it an ideal medication for this purpose. Specifically: methadone can be given orally; methadone has a slow onset of action (thus precluding a "euphoric rush" as is experienced when a short-acting opioid such as heroin is injected); methadone has a long-duration of action permitting it to be taken no more frequently than once a day; and when given in appropriate constant daily dosage methadone produces an extremely high level of tolerance to the usual opioid actions such as euphoria, respiratory depression, sedation, etc.

EFFICACY OF METHADONE MAINTENANCE TREATMENT

The efficacy of methadone maintenance is indisputable. It has been endorsed by government as well as academic and clinical authorities in the US and throughout the world. Just a few illustrations follow:

> **National Institute on Drug Abuse**, 1983[2]: "To argue that methadone maintenance is not effective is to ignore the results of the best designed research studies and the consensus of varied groups of experts."
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> **Institute of Medicine**, 1995[3]: the effectiveness of methadone treatment "… has been established in many studies conducted over three decades …"
>
> **NIH** Consensus Report, 1997[4]: "The safety and efficacy of narcotic agonist (methadone) maintenance treatment has been unequivocally established."
>
> **US Centers for Disease Control**, 2002[5]: "Methadone maintenance treatment is the most effective treatment for opiate

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[2] Cooper JR, Altman F, Brown BS, Czechowicz D., *Research on the Treatment of Narcotic Addiction: State of the Art*. Rockville, MD: National Institute on Drug Abuse; 1983:xv. US Department of Health and Human Services (ADM) 83-1281.

[3] Institute of Medicine, *Federal Regulation of Methadone Treatment*. Rettig RA, Yarmolinsky A, eds. Washington, DC: National Academy Press; 1995

[4] *Effective Medical Treatment of Opiate Addiction*. NIH Consensus Statement 1997 Nov 17-19; 15(6): 4; accessed 29 Nov. 2011 at: http://consensus.nih.gov/1997/1998TreatOpiateAddiction108PDF.pdf

[5] IDU/HIV Prevention: *Methadone Maintenance Treatment*, February 2002; Accessed 29 Nov. 2011 at: http://www.cdc.gov/idu/facts/MethadoneFin.pdf

addiction. … *Methadone maintenance treatment has important benefits for addicted individuals and for society.*" (emphasis in original)

WHO, 2008[6]: "… substitution therapies such as methadone are still the most promising method of reducing drug dependence."

EFFECTS (AND LACK OF EFFECTS) OF METHADONE MAINTENANCE: CRAVING AND TOLERANCE

Constant daily doses of methadone cause a marked reduction or complete elimination of *craving*. Craving is the intense "need" for a substance that addicts find very difficult to put into words, but to which they attribute the inability to quit using – or to remain abstinent once they have, for a while, stopped. The phenomenon of craving is something to which long-term smokers can readily relate. They, too, are usually unable to convey to non-smokers what it is that will drive them to almost any lengths, at any time, in any weather, and regardless of cost, to obtain a cigarette. It is precisely this overwhelming desire for opioids that methadone maintenance suppresses.

There is no "right" dose of methadone applicable to all patients, and even for an individual the dosage might from time to time be modified based on clinical assessment and patient request. There is no relationship whatever between any particular dosage level and the "severity of dependence," likelihood of relapse, or any other prognostic measure (except that doses of less than 60 mg per day are for most patients associated with poorer outcome).

It must be noted that for virtually all dependencies, including those related to opioids, nicotine and alcohol, a significant proportion of individuals can discontinue use, seemingly at will, with or without treatment (medication-based or drug-free). It is widely accepted that genetics play a major role both in determining who becomes dependent, and who is able quite readily

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[6] Bulletin of the World Health Organization 2008. 86(3):164-165; accessed 29 Nov. 2011 at: http://www.who.int/bulletin/volumes/86/3/08010308.pdf

to stop use. For example, a very recent report related to nicotine addiction concluded: "…it is now well understood that genetic diversity is one of the components that contributes to differences in the risk of substance-use disorders, including smoking onset, amount of smoking, *and smoking desistance*." (Emphasis added; Boardman JD *et al. Demography,* (2011) 48: 1517-1533; accessed 29 Nov. 2011 at: http://www.springerlink.com/content/dj722l4072562181/) With alcohol, as well, the distinction was made some 75 years ago that in contrast to the alcoholic, most people "drink from choice and not from necessity." W.D. Silkworth, Med Rec 1937. 145:249-251. Those who fall in the latter category (*i.e.,* "alcoholics") generally need and often respond very well to on-going attendance at AA meetings and/or medication. And in the case of heroin dependency, it was found that "… of all the men addicted [to heroin] in Viet Nam, only 12% have relapsed to addiction … at any time in the last 3 years [following return to US]." (Robins, LN *et al*, *American Journal on Addictions*, 19:203-211, 2010).

However, the fact that some individuals are able, for whatever reasons, to discontinue drug use without any treatment does not diminish the real need of other individuals for treatment. As noted above, methadone is uniquely well-suited for treating individuals who require treatment for opioid drug dependence because, in addition to markedly reducing or eliminating craving, constant daily administration of methadone also leads to establishment of a high degree of *tolerance* to the effects not only of methadone itself but to those of all other opioids. The phenomenon of tolerance is key to understanding how and why methadone maintenance does not cause euphoria, cognitive impairment, sedation, or any other effect that would warrant concern over a patient's ability to function normally in every respect and in every type of work.

Simply put, tolerance is defined as the body's becoming less responsive, as a result of repeated exposure, to a medication's pharmacological actions. An example of tolerance experienced by many people is that which results from repeated administration of the common nose drops taken to relieve a "stuffy nose." The first few times the drops are administered the nasal passages usually respond promptly and the patient feels great. Initially relief continues to be obtained with repeated administration, but quite quickly, within a matter of just a few days, the nasal passages become tolerant to the

medication and no longer respond at all – even if huge volumes were to be administered.

Another example that is a painful (!) reality to patients suffering severe pain, and to their clinicians, is the tolerance that develops to the pain-killing effect of narcotics. Again, the initial response to the drug usually is gratifying, but over the course of just a few weeks repeated administration leads to tolerance to the analgesic effect of even the most potent narcotics. Furthermore, administration of any one of the many narcotic drugs causes the body to develop a tolerance not just to that medication, but to the entire family of narcotic substances. Thus, to the dismay of patients and physicians alike, when a pain associated with a chronic (or terminal) illness has been treated with, for example, morphine, one can not achieve analgesia simply by switching to codeine, or fentanyl, or oxycontin, or methadone, etc.

Although the phenomenon of tolerance can result in a drug becoming less effective in the situations described above, tolerance to methadone makes it possible for methadone to be used as a maintenance medication to satisfy and relieve cravings for other narcotic drugs without the patient experiencing other unwanted side effects such as cognitive impairment or sedation. (Note that tolerance to the ability of methadone to reduce or eliminate craving does *not* occur.) Accordingly, a person who has developed tolerance because of constant daily administration of methadone does not experience the same pharmacological actions that, in the opioid-naïve individual, would likely interfere with cognition, ability safely to drive or operate machinery or, indeed, could prove lethal. This statement is not conjecture but based on evidence. To cite one highly authoritative source, the US Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA), stated in a 2005 publication, "Long-term methadone … therapy is associated with few side effects." (U.S. Department of Health and Human Services, SAMHSA, *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs,* 2005, Chapter 3, p. 33; accessed 29 Nov. 2011 at: http://www.ncbi.nlm.nih.gov/books/NBK25695/) Tolerance is the reason for this favorable aspect of methadone maintenance. Nothing whatever is said in this Government-produced manual that would suggest current methadone maintenance treatment should be a bar to professional licensure or safe practice of a nurse. The conclusion reached by SAMHSA regarding

the absence of troublesome side effects attributable to maintenance doses of methadone is echoed in an article that appears in the recent and authoritative textbook *Substance Abuse, A Comprehensive Textbook* (4th edition, 2005). The article by J. Lowinson, *et al.*, "Methadone Maintenance" is Chapter 39 and states,

> "Methadone maintenance, itself, does not impair the normal functioning of patients. Psychomotor performance tests that measure skills such as reaction time, driving ability, intelligence, attention span, and other important abilities were administered to methadone patients, volunteers, and normal college students with no drug history. The performance of methadone patients did not differ from those of normal volunteers or college students. Studies of patients' driving records in both Texas and New York found that the driving records of methadone patients did not differ significantly from those of the driving population at large. On the Wechsler Adult Intelligence Scale, the mean intelligence quotient (IQ) of methadone patients at the time of entry into treatment was slightly higher than that of the general population. Ten years later, the same patients showed even higher scores. Based on these studies, it can be concluded that methadone maintenance does not impair normal functioning or intellectual capacity."

Substance Abuse, A Comprehensive Textbook, at pp. 622-623 (citations omitted).

The unparalleled efficacy of methadone in preventing relapse to uncontrolled, self-administered opioid use, and all the many adverse effects with which such use is associated, is attributed *both* to its ability to suppress craving and also to the very high degree of tolerance that, at appropriate maintenance doses, precludes euphoria even if supplemental narcotics (heroin, additional methadone, oxycodone, etc.) are taken. In the words of the World Health Organization more than four decades ago:

> "Methadone maintenance is the continuing daily oral administration of methadone under adequate medical supervision, the dose being adjusted *(a)* to prevent the

> occurrence of abstinence phenomena, *(b)* to suppress partially or completely any continuous preoccupation with the taking of drugs of the morphine type, and *(c)* to establish a sufficient degree of tolerance and cross tolerance to blunt or suppress the acute effects of such agents."

(WHO Expert Committee on Drug Dependence, TRS 460, 1970, p. 22; accessed Nov. 29, 2011 at: http://whqlibdoc.who.int/trs/WHO_TRS_460.pdf)

NURSES CAN SAFELY PRACTICE THEIR PROFESSION WHILE RECEIVING METHADONE MAINTENANCE TREATMENT

According to the Division of Professional Health Management Programs ("PHMP") document "Standard Operating Procedures," the "primary responsibility of the PHMP is to protect the citizens of the Commonwealth from unsafe practice by Commonwealth-licensed practitioners diagnosed with physical and/or mental impairments." (Deposition Exhibit P-6 at p. 26) The "Standard Operating Procedures" also state that "[t]his responsibility is fulfilled through the identification and referral to appropriate treatment of such licensed professionals, and the case management and monitoring of their progress in recovery for a period of at least three years." However, the written policies regarding professionals on methadone maintenance treatment which I have reviewed as described below make it clear that PHMP treats licensed professionals who receive methadone maintenance treatment differently from other opioid dependent professionals. This disparate treatment is unwarranted and unnecessary: it affords no special protection to the citizens of Pennsylvania from "unsafe practice," and has no medical, scientific or empirical basis.

It is my firm opinion, based on extensive personal experience and a comprehensive knowledge of the published evidence on this subject, that there is no basis for the assumption that methadone maintenance, *per se*, interferes in any way with the ability to function as a nurse. Licensed professionals who receive methadone maintenance treatment are less likely to suffer a relapse in drug use as compared with opioid dependent persons who are not receiving maintenance treatment. In addition, methadone maintenance treatment does not adversely affect their ability to practice their

professions. Discrimination against persons receiving methadone maintenance treatment does not promote PHMP's stated mission.

PHMP PRE-JUNE 2008 POLICY PROHIBITING LICENSED PERSONS WHO ARE RECEIVING METHADONE MAINTENANCE TREATMENT FROM PRACTICING THEIR PROFESSIONS.

I have reviewed Deposition Exhibit P-2, which describes PHMP's written policy relating to licensed persons receiving methadone maintenance treatment. I also attended and have reviewed the transcript of the first part (August 25, 2011) of the deposition of Mr. Kevin Knipe, who testified that he has been the Program Manager of PHMP since December 2003, and that Exhibit P-2 describes the policy in effect until at least June 2008.[7] This pre-June 2008 policy reflects clearly an absolute prohibition barring persons receiving methadone maintenance treatment from practicing their respective professions, including nursing. For the reasons already stated, it is my opinion that there is no medical, scientific or empirical basis for this pre-June 2008 policy.

PHMP POST-JUNE 2008 POLICY REQUIRING ADDITIONAL NEUROPSYCHOLOGICAL TESTING FOR LICENSED PERSONS WHO ARE RECEIVING METHADONE MAINTENANCE TREATMENT

I have also reviewed Deposition Exhibit P-27, a memorandum dated May 28, 2008 from Mr. Knipe to Mr. Merenda, the Commissioner of the Pennsylvania Bureau of Professional and Occupational Affairs ("BPOA"), and Mr. Vessella, the Deputy Commissioner of BPOA, which describes a proposal to change the pre-June 2008 policy. Although I have not seen any document which makes it clear when or whether this proposal was adopted, I am aware from attending and reviewing the transcript of Mr. Knipe's August 25, 2011 deposition session that Mr. Knipe testified that the proposal

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[7] I did not attend the second part of Mr. Knipe's deposition on November 9, 2011, and only received the transcript of the November 9, 2011 session several days ago. Accordingly I reserve the right to supplement this report after I have had time to thoroughly review the additional transcript.

was adopted in June 2008 and so I will refer to the proposed new policy as the "post-June 2008 policy." According to Mr. Knipe's deposition at pages 61 and 62, he was the author of this post-June 2008 policy. The post-June 2008 policy requires that licensed persons receiving methadone maintenance treatment, unlike other licensed persons who are or who are known to have been opioid dependent, must obtain "neuropsychological testing" to demonstrate their fitness to practice before they can return to work. I have also reviewed the documents that the defendants have identified as the basis for or relating to this "neuropsychological testing" requirement.[8] Nothing in Mr. Knipe's testimony or in the documents listed in the footnote supports the claim that such testing is necessary in order to assure that nurses receiving methadone maintenance treatment are able to practice their profession safely. For the reasons already stated, it is my opinion that there is no medical, scientific or empirical basis for this post-June 2008 policy. In my medical opinion, there is no justification for singling out licensees receiving "maintenance" treatment for opioid drug dependence and demanding of them, and only them, special requirements.

MS. REYNOLDS' RESPONSE TO METHADONE TREATMENT

I have reviewed several letters of reference for Ms. Reynolds from employers for whom she worked as a nurse and covering periods when she was receiving methadone maintenance treatment beginning in 1997. These letters corroborate the fact that Ms. Reynolds was able to work skillfully and safely as a nurse while receiving methadone maintenance treatment.

In addition, Ms. Reynolds was examined and tested by a nationally respected addiction scientist (one relied upon by the State of Pennsylvania for such evaluations), Dr. George Woody, who was aware that she was receiving methadone maintenance treatment and whose conclusion was that she could safely be permitted to work as a nurse. Whatever stereotypes one might harbor regarding patients receiving this form of medical treatment, this is evidence that the stereotype is unwarranted, and that her participation in a

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[8] *See* Deposition Exhibits P-36 and P-37 (marked in Mr. Knipe's deposition on August 25, 2011), and P-45, P-46 and P-47 (marked in Mr. Knipe's deposition on November 9, 2011).

methadone maintenance program was not a basis for license revocation or denial of permission to work as a nurse.

DURATION OF METHADONE MAINTENANCE TREATMENT

There is neither evidence nor logic to support a time-limit on the duration of methadone maintenance treatment. Since dependence on opioids is a condition that – to date – defies cure, it is clear that regardless of duration or degree of success of treatment, the majority of individuals relapse when methadone maintenance is terminated (the same reality applies to every other form of opioid addiction treatment, whether with or without use of medication, and the concept of "incurable but treatable" has been accepted for well over half a century when applied to dependence on alcohol). Accordingly, any policy that demands that someone effectively maintained on methadone detoxify is not only counter to the consistent evidence of many decades, but is destined to expose the individual as well as the public, and/or the workplace, to grave and totally avoidable risk.

Ongoing treatment with methadone, while not interfering with an individual's ability to function, is the best assurance known against relapse; overruling the decision of a clinical care provider and the perceived self-interest of the patient is irresponsible and indefensible, and it is not hyperbole to state that it can have fatal consequences.

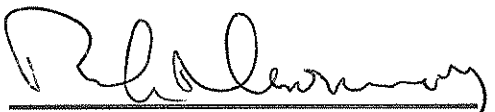
METHADONE MAINTENANCE IS GOVERNED BY STRINGENT FEDERAL AND STATE REGULATION, AND MONITORING BY STANDARD–SETTING AGENCIES

To my knowledge there is no other form of medical treatment – for any condition – that is subject to the same broad (and yet very detailed) range of rules, regulations and standards, and as stringent a monitoring system, as methadone maintenance. Thus, it must be provided exclusively by "comprehensive treatment programs" that are required to offer, along with the medication itself, a wide array of counseling services, medical screening, etc. Federal law demands on-going routine urine toxicology to identify the possible use/misuse not only of opioids, but of a number of other drugs as well. Methadone may be administered and dispensed exclusively by trained nursing personnel working in such comprehensive programs; the nurses are

expected not only to hand out medicine but also to observe each patient and, if there is any reason for concern over either the physical or mental status of any patient, to alert the physician. Given the stringent rules governing the number of "take-home" doses that may be given, and the criteria that must be met before attendance can be reduced to less than 6 or 7 days per week, this provides for a degree of close and on-going direct clinical observation that is unique.

SUMMARY

Based on extensive first-hand experience in the field of methadone maintenance treatment of opioid dependence, a comprehensive familiarity with reports that have appeared in the worldwide professional literature over the course of decades, and my review of the records provided to me with respect to this case, it is my considered medical opinion that the fact that Ms. Reynolds is receiving methadone maintenance treatment is not a basis for denying her licensure and permission to work and function as a nurse (under the pre-June 2008 PHMP policy), or for subjecting her to neuropsychological or any other testing not required of persons using other forms of treatment for opioid drug dependence (under the post-June 2008 PHMP policy). The fact that Ms. Reynolds is receiving methadone maintenance treatment is not a basis for concern regarding the health and welfare of patients who would be in her care.



Robert G. Newman, MD, MPH

December 1, 2011